

105TH CONGRESS  
2D SESSION

# H. R. 3758

To require persons who undertake federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 1998

Mr. SANDERS (for himself, Mr. CAMPBELL, Mr. KENNEDY of Rhode Island, Mr. ROHRABACHER, Mr. WAXMAN, Mr. STARK, Mr. BERRY, Ms. WOOLSEY, Mr. DEFazio, Mr. KUCINICH, Mr. FALEOMAVAEGA, and Mr. BOUCHER) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To require persons who undertake federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Health Care Research  
5       and Development and Taxpayer Protection Act”.

1 **SEC. 2. REASONABLE PRICE AGREEMENT.**

2 (a) IN GENERAL.—If any Federal agency or any non-  
3 profit entity undertakes federally funded health care re-  
4 search and development and is to convey or provide a pat-  
5 ent or other exclusive right to use such research and devel-  
6 opment for a drug or other health care technology, such  
7 agency or entity shall not make such conveyance or pro-  
8 vide such patent or other right until the person who will  
9 receive such patent or other right first agrees to a reason-  
10 able pricing agreement with the Secretary of Health and  
11 Human Services or the Secretary makes a determination  
12 that the public interest is served by a waiver of the reason-  
13 able pricing agreement provided in accordance with sub-  
14 section (c).

15 (b) CONSIDERATION OF COMPETITIVE BIDDING.—In  
16 cases where the Federal Government conveys or licenses  
17 exclusive rights to federally funded research under sub-  
18 section (a), consideration shall be given to mechanisms for  
19 determining reasonable prices which are based upon a  
20 competitive bidding process. When appropriate, the mech-  
21 anisms should be considered where—

- 22 (1) qualified bidders compete on the basis of  
23 the lowest prices that will be charged to consumers;  
24 (2) qualified bidders compete on the basis of  
25 the least sales revenues before prices are adjusted in

1       accordance with a cost based reasonable pricing for-  
2       mula;

3           (3) qualified bidders compete on the basis of  
4       the least period of time before prices are adjusted in  
5       accordance with a cost based reasonable pricing for-  
6       mula;

7           (4) qualified bidders compete on the basis of  
8       the shortest period of exclusivity; or

9           (5) qualified bidders compete under other com-  
10      petitive bidding systems.

11   Such competitive bidding process may incorporate require-  
12   ments for minimum levels of expenditures on research,  
13   marketing, maximum price, or other factors.

14       (c) WAIVER.—No waiver shall take effect under sub-  
15   section (a) before the public is given notice of the proposed  
16   waiver and provided a reasonable opportunity to comment  
17   on the proposed waiver. A decision to grant a waiver shall  
18   set out the Secretary’s finding that such a waiver is in  
19   the public interest.

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